

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration Florida District 555 Winderley Place Suite 200 Maitland, Florida 32751

Telephone: 407-475-4700 FAX: 407-475-4768

VIA FEDERAL EXPRESS

Re:

Customs Entry No. WKV-0035441-0

Product: Beltfish

WARNING LETTER

FLA-02-24

February 4, 2002

Mauricio Rafael Barcia, President Lubar Seafood Corp. 2665 S. Bayshore Drive Suite 900 Miami, FL 33133

Dear Mr. Barcia:

The Food and Drug Administration (FDA) attempted to sample a shipment of Beltfish in accordance with our notice of sampling dated, January 9, 2002 under entry number WKV-0035441-0 and found that the entire shipment was not available for FDA examination. Title 21 Code of Federal Regulations Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U.S. Customs Service (Customs) to order redelivery of the unavailable portion of the entry.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Mr. Mauricio Rafael Barcia Page 2 February 4, 2002

Your written reply should be addressed to the Food and Drug Administration, Attention: Christine M. Humphrey, Compliance Officer, 6601 NW 25th Street, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Emma R. Singleton Director, Florida District

CC: Thomas Winkowski
U.S. Customs Service
P.O. Box 02-580

Miami, Florida 33102-5280